



REMARKS

Claims 1 - 4, 8, 11 - 17, 19, 20, 23, and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke. In response, each of the independent claims 1, 15, and 23 have been amended to clarify the following differences between the present invention and endotracheal tube described by Brekke:

1. The present invention is a nasal catheter that provides air/oxygen to supplement the patient's spontaneous breathing. Each of the independent claims have been amended to clarify that the present invention is an "open" system that does not obstruct the patient's spontaneous breathing. Brekke teaches away from the present invention by disclosing a "closed" system in which spontaneous breathing is blocked by the endotracheal tube cuff 20 in the patient's trachea and the inflatable barrier 18 sealing the back of the patient's oral cavity. As with other types of endotracheal tubes, the Brekke device is intended for use with a ventilator. The patient is solely dependent on the respiratory cycle and gas volume supplied by the ventilator. In particular, Brekke discusses that his device can be used to administer anesthetic gases to a patient. In contrast to the present invention, a "closed" system is required for this purpose to prevent the escape of anesthetic into the surrounding room and to control the anesthetic dose to the patient.
2. The distal end of the present nasal catheter supplies air/oxygen into the patient's distal nasopharynx or oropharynx. In contrast, the distal end of the endotracheal tube disclosed by Brekke extends past the patient's nasopharynx, oropharynx, and larynx, and into the patient's trachea.
3. All of the independent claims require a gas flow rate of approximately 4 to 40 liters per minute. This high flow rate of gas is delivered into the patient's distal nasopharynx or oropharynx, at a point relatively high in the patient's respiratory

tree. A portion of this gas flows into the patient's trachea and lungs to deliver oxygen and flush carbon dioxide from the patient's lungs. In addition, if the gas delivered by the catheter has an elevated oxygen content, it will tend to enrich the oxygen content of all of the gas in the patient's respiratory tree, and thus makes the patient's spontaneous breathing more effective. However, a large portion of the gas exiting the catheter is exhaled or flows out of the patient's airway and is lost. Flow rates of 4 to 40 liters per minute are physiologically possible with "open" systems because excess gas can escape from within the patient, but not with a "closed" system such as Brekke.

Regarding claims 2 - 3, 15 - 22 and 24, nothing in Brekke teaches or suggest a catheter that can be trimmed to a desired length. The endotracheal tube disclosed by Brekke has a fixed length. The cuff at the distal end of the endotracheal tube and the conduits at the upper end of the Brekke device would make it very difficult to trim such a device while maintaining its intended functionality. Column 4, lines 46 *et seq.* of the Brekke patent discusses adjusting the position of the tube, but not trimming its length. With regard to claims 24 and 25, nothing in Brekke teaches or suggests cutting the catheter so its distal tip will have a desired position relative to the patient's uvula.

Claims 5, 6, and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Dali et al. Claims 7 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Spofford et al. Claims 9, 10, 21, 22, 26, and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Daniell et al. In response, Applicant notes that these are dependent claims and restates the previous comments concerning amended independent claims 1, 15, and 23.

Favorable reconsideration is respectfully requested.

Respectfully submitted,

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Marked Up Version of Amended Claim 1:

1. (twice amended) A nasopharyngeal catheter to deliver a flow of air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration, said nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration;

a delivery tube adapted to extend below the patient's nostril connected to the proximal end of the nasal catheter; and

a gas source delivering a flow of air/oxygen at a rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter into the patient's distal nasopharynx or oropharynx.

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Marked-Up Version of Amended Claim 15:

15. (twice amended) A nasopharyngeal catheter to deliver a flow of air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration, said nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration, said catheter being made of a flexible material that can be trimmed to a desired length;

a delivery tube adapted to extend below the patient's nostril having a connector for removable attachment to the proximal end of the nasal catheter; and

a gas source delivering a flow rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter into the patient's distal nasopharynx or oropharynx.

Marked-Up Version of Amended Claim 23:

23. **(amended)** A method for providing a supplemental flow of air/oxygen to a spontaneously breathing patient, the method comprising:

advancing a nasopharyngeal catheter through a patient's nostril until the distal tip of the catheter is located in the patient's distal nasopharynx or oropharynx **without obstructing the patient's spontaneous respiration**; and

supplying air/oxygen through the catheter at a flow rate of approximately 4 to 40 liters per minute **into the patient's distal nasopharynx or oropharynx**.